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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,696	07/24/2002	Yukoh Hiei	0760-0304P	5503

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EXAMINER	
HWU, JUNE	

ART UNIT	PAPER NUMBER
1661	

NOTIFICATION DATE	DELIVERY MODE
01/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/089,696	HIEI ET AL.	
	Examiner	Art Unit	
	JUNE HWU	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12,15,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) *9,12,15,18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2008 has been entered.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Status of the Claims

Claims 1-8, 10-11, 13-14, 16-17, and 19-20 are cancelled; claims 9, 12, 15, 18, and 21 are withdrawn; claims 22-30 will be examined on the merits.

The objections to the claims have been withdrawn due to Applicants' amendment to the claims.

The rejection under 35 USC 112 (2nd paragraph) has been withdrawn due to Applicants' amendment to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "plant cell" in 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konzak et al (U.S. Patent No. 6,362,393) in view of Lyznik et al (The Plant Journal (1995) 8(2), 177-186).

The claims are drawn to a method of plant transformation comprising centrifuging the plant, plant cell, or plant tissue of rice or maize under an acceleration of 1000G to 150,000G, and contacting the plant, plant cell or plant tissue with *Agrobacterium* wherein the contacting step is carried out after or simultaneously of said centrifugation between 1 second to 4 hours.

Konzak et al teach a method of centrifuging microspores (col. 4, lines 6-9) of rice or corn (also known as maize from the family *Gramineae*, a monocot and an angiosperm) (col. 6, lines 29-32) at the acceleration of 100G for 3 minutes (col. 16, line 1) prior to gene introduction. Microspore is defined as "male gametophyte of a plant, including all stages of development form meiosis through formation of the mature pollen grain, which is a plant tissue (col. 6, lines 19-21). Moreover, Konzak et al taught that gene transformation could occur at any time of the procedure (col. 4, lines 30-36) by using *Agrobacterium tumifaciens* (col. 12, lines 53-56).

Konzak et al do not teach the centrifugation speed of 1000G to 150,000G.

Lyznik et al teach that protoplasts were harvested in tubes pelleted by centrifugation for 5-10 sec at 1000 g, and suspended in GUS extraction buffer (page 183, col. 2, last paragraph).

It would have been obvious to one of ordinary skill in the art to use the method of promoting gene introduction into plant cells by centrifuging the plant cells or plant tissues before gene introduction by applying *Agrobacterium* as taught by Konzak et al, and to modify that method by adjusting the centrifugal acceleration as taught by Lyznik et al given the advantage of separating the tissues from the medium at higher speed. With regard to the use of protoplast as taught by Lyznik et al, one of ordinary skill in the art would have try to use plant tissue because if the protoplast could withstand the high centrifugation speed then the plant tissue could also. One would have been motivated to do so, given the effectiveness of separating plant tissue by centrifugation. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Konzak et al in view of Lyznik et al because the contacting step with *Agrobacterium* of plant cells or plant tissues simultaneously or after centrifugation would be a choice of experimental design and is considered within the purview of the cited prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Applicants' arguments filed August 22, 2008 have been fully considered but they are not persuasive.

Applicants urge that the essential features of the instant invention are "centrifuging a plant sample" and "bringing the plant sample into contact with *Agrobacterium*." In addition, that there was an unexpected effect from this process and cites support data in the Hiei declaration dated September 2, 2008 (herein after Hiei Declaration 2008) (response p. 10).

This argument is not found persuasive because Hiei Declaration 2008 (pp. 2-3) states, "callus formation from scutellar tissue was better on the callus induction media from pre-centrifuged embryos than from non-treated embryos in both Koshihikari (Figure 1) and IR64 (Figure 2)." The control without centrifugation also showed callus formation. Fig. 1 of Hiei Declaration 2008 showed unexpected result with only Koshihikari variety centrifuged at 20,000 xg for 10 minutes; however the instant claims recite a broad range of centrifugation between 1000G to 150,000G for 1 second to 4 hours. The MPEP 716.02(d) states, "objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support." Thus, the unexpected results must occur over the entire claimed ranged and the Hiei Declaration 2008 does not cover the entire claim range. Therefore, the limited showing of unexpected results is not sufficient to support the breadth of the instant claims. With regard to "centrifuging a plant sample" one of ordinary skill in the art would have been motivated

to centrifuge the plant tissue because centrifugation is an effective process for separating the plant tissue.

Applicants urge that the on page 2, line 12-14 of the instant specification which reads, "On the other hand, studies for changing the plant tissue before infection of *Agrobacterium* to a physiological state in which the genes are likely to be introduced have been scarcely made" is clearly different from the prior art (response p. 10).

This argument is not found persuasive because Applicants have not found support for this statement. The cited references to pretreatment of plant tissue on page 2, lines 19-20 of instant specification recite Bidney et al, 1992 which discuss particle treatment and Trick et al which discuss ultrasonication treatment. These references do not state that the physiological state is scarcely changed when the plant tissue to which a gene is introduced by centrifugation before infection of *Agrobacterium*. Furthermore, the claims do recite the change in "physiological state." Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants urge that the data in the Hiei Declaration submitted on November 13, 2007 (herein after Hiei Declaration 2007) support that the cell division of the scutellum is activated by centrifugation treatment resulting in larger and heavier scutellum (response pp. 10-11).

This argument is not found persuasive because Table 1, Fig. 1, and Fig. 2 of Hiei Declaration 2007 discuss GUS activity and not size of the scutellum. Applicants may be referring to Hiei Declaration 2008. If Applicants are referring to Hiei Declaration 2008, then the difference between the control and the centrifuged fresh weight of embryos do not show significant differences. With regard to Fig. 2 of Hiei Declaration 2008, the immature embryos of

IR64 did not show significant difference in size. Moreover, the claims are not limiting to the weights of the scutellum.

Applicants urge that the present invention is to a technique in which the "physiological state" is "changed" by centrifugation treatment (response p. 11).

This argument is not found persuasive because as stated above the change on "physiological state" is not recited in the claims.

Applicants urge that Tables 1-3 show transformation efficiency and the results are consistent and cite the Hiei Declaration 2007 (response p. 12).

This argument is not found persuasive because as stated in the Final Rejection mailed February 22, 2008 on page 8 Tables 1-3 do not show significant differences between the sampled centrifugal accelerations. With regard to the Hiei Declaration 2007, Table 1 shows some GUS activity with 760 xg. The evidence of nonobviousness does not provide support for the instant claims broad range of centrifugation of 1000G to 150,000G for 1 second to 4 hours. Objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support. See MPEP 716.02(d).

The affidavit under 37 CFR 1.132 filed September 2, 2008 is insufficient to overcome the rejection of claims 22-30 based upon the rejection under 35 USC 103 as set forth in the last Office action because: The callus formation from the scutellar tissue was better on the callus induction media from the pre-centrifuged embryos but callus formation also occurred in the non-centrifuged cultures. Fig. 1 shows a fair amount of control fresh weight of embryos when compared to the centrifuged fresh weight embryos. Fig. 2 of immature embryos of IR64 does not show significant difference between the control and centrifuged embryos. In addition, the

claims recite centrifuging up to 150,000G for 4 hours. The data provide support for 20,000 xg for 10 minutes for the Koshihikari variety and 1,100 xg for 10 minutes for the IR64 variety.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June Hwu

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638